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Food and Drug Administration
Center for Devices and Radiological Health
Regulations Staff (HFZ-2 15)
1350 Piccard Drive
Rockville, Maryland 20857

Re: Classification Petition for the SCRAM™ Bracelet (and Collectively, the SCRAM™ System) as a Class I Medical Device in Accordance with Section 513(f) of the Food Drug and Cosmetic Act ("FDCA")

Dear Sir or Madam:

The SCRAM™ System is a postamendment device. As a result, this device is automatically classified by Section 513(f)(1) of the FDCA into Class III. Since there appears to be no specific device within this type, undersigned counsel, on behalf of the manufacturer, Alcohol Monitoring Systems ("AMS"), this petition for reclassification of the SCRAM™ Bracelet (or alternatively, the SCRAM™ System) into Class I (non-reserved) is made pursuant to section 513(f)(2) of the FDCA and the regulations under § 860.134 (21 C.F.R. § 860.134).

Under section 513(f)(2) of the FDCA, the agency is authorized, in accordance with section 513(d)(2)(A), to exempt a generic type of device from, among other things, the requirement of premarket notification in section 510(k) of the act (21 U.S.C. 360(k)) after stating the reasons for making such requirement inapplicable. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA.[1]

[1] 63 Fed. Reg. 10792.

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There are three parts to the SCRAM™ System:

SCRAM™ Bracelet

SCRAM™ Modem

SCRAM™ Network

The heart of the SCRAM™ System is the SCRAM™ Bracelet, which is attached to the client's ankle and measures ethanol emitted through the skin. The attached petition requests reclassification of the SCRAM™ Bracelet as a Class I non-reserved device. The SCRAM™ Modem and SCRAM™ Network are Class I non-reserved devices (i.e. Medical Image Communications Devices (21 CFR § 892.2020) and Medical Image Storage Devices (21 CFR § 892.2010)).

This petition presents evidence that the SCRAM™ Bracelet conforms to the criteria described in 513(a)(1)(A) for Class I, non-reserved devices and that there are sufficient regulatory controls, such as guidance documents, conformance to safety standards, and compliance with the Quality System Regulation will provide reasonable assurance of the safety and effectiveness of the SCRAM™ Bracelet for its intended use.

Pursuant to FDA policy,[2] the reclassification process should be used to ensure that the proper level of regulatory control is applied to a device type. The Safe Medical

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[2] The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry *available at* http://www.fda.gov/ohrms/dockets/98fr/LEAST%20BURDENSOME%20FINAL1.DOC. ; *See* S. REP. NO. 105-43, at 2. The Senate report emphasizes a series of changes directed to improving certainty and clarity of agency rules, making the approval process less burdensome and thereby improving access. These include facilitating reclassification and/or approval of device applications by allowing FDA to consider historical data, defining review time frames more clearly, and explicitly stating the relationship of labeling claims to approval and clearance of medical devices

Devices Act of 1990 (SMDA) and FDAMA, by facilitating the reclassification and exemption processes, reinforced the Medical Device Amendments of 1976 directive to continue to consider the lowest appropriate level of regulatory control sufficient to provide reasonable assurance of the safety and effectiveness of the device. As a result, petitioner is taking advantage of this tool and submitting this reclassification petition pursuant to FDA guidance.

Thank you in advance for your prompt attention to this matter. Further questions and comments should be sent directly to C. Humphrey & Associates, P.A., ATTN: Christine M. Humphrey, Esq. at the following address: 1001 Brickell Bay Drive, Suite 2002, Miami, Florida 33131, (785)245-0440 or by email at cmh@humphrey-law.com.

Very truly yours,

Christine M. Humphrey, Esq.
C. Humphrey & Associates, P.A.

Enclosures